

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<b>LANNETT COMPANY, INC.</b>	<b>:</b>	<b>CIVIL ACTION</b>
	<b>:</b>	
<b>v.</b>	<b>:</b>	<b>NO. 08-3920</b>
	<b>:</b>	
<b>CELGENE CORPORATION</b>	<b>:</b>	

**MEMORANDUM OPINION**

**Savage, J.**

**March 29, 2011**

In its motion to enforce a purported settlement agreement, plaintiff, Lannett Company, Inc. (“Lannett”) claims that an oral agreement to settle this case was reached during a pretrial conference and later memorialized in its counsel’s letter to the attorney for defendant Celgene Corporation (“Celgene”). Lannett contends that although it complied with all conditions precedent, Celgene has refused to perform its part of the bargain. Celgene, in response, argues that there was no final agreement, but only an agreement to negotiate one. Celgene disputes that Lannett’s counsel’s letter confirmed that an agreement had been made.

**Background**

Lannett, a pharmaceutical manufacturer of generic drugs, has sued Celgene, the manufacturer of Thalomid, which is the brand name for thalidomide, under the antitrust laws. It alleges that Celgene, which held the expired patent for Thalomid, refuses to sell it Thalomid pills needed to conduct a bioequivalence study, a necessary step to obtain Federal Drug Administration (“FDA”) approval to market a generic thalidomide drug. Without the pills, Lannett cannot conduct the requisite study. Lannett asserts that Celgene’s withholding the pills prevents any generic drug manufacturer from competing in

the thalidomide market.

Citing the notorious side effects of the drug, Celgene insists that Lannett satisfy numerous conditions it contends are necessary to protect it from any claims before it will sell the pills to Lannett. Celgene argues that it is Lannett that is unwilling to agree to terms for the sale.

Lannett contends that after the parties had reached an agreement in a meeting in chambers, Celgene repeatedly changed the terms of the agreement by modifying the conditions, demanding more each time Lannett satisfied the agreed upon conditions. Simply stated, Lannett argues that Celgene has employed a moving target that is impossible to hit.

The question is whether the parties entered into an agreement to settle the action. To answer this question, we must look to the nature and the circumstances of the parties' communications. Central to the inquiry is determining the intent of the parties during those discussions.

Lannett contends that the parties reached an agreement at a settlement conference on July 28, 2009. There is no written settlement agreement or draft resulting from the conference.

According to Lannett, at the conference, it agreed to dismiss its antitrust claim against Celgene in return for Celgene's selling Lannett a quantity of Thalomid (thalidomide) pills necessary to conduct Lannett's pilot bioequivalence study. As a condition of the sale, Lannett was to provide Celgene with an indemnification agreement, liability insurance covering Celgene, a study protocol for the bioequivalence testing in a form approved by the FDA, and Lannett's adverse drug event reporting history for the previous five years.

Lannett claims that it has met all of the conditions. It has produced a signed indemnification agreement drafted by and submitted by Celgene, a copy of its liability insurance policy, the study protocol and its adverse drug event reporting history.

Celgene contends that the insurance policy has inadequate limits of liability and does not cover human clinical trials. It also questions the efficacy of the study protocol's safety.

Contrary to Lannett's contention that its counsel's September 24, 2009 letter to Celgene's counsel memorialized the parties' agreement, it actually demonstrates that the parties were still in negotiations and were attempting to reach an agreement. It specifically notes several areas that remained in dispute and subject to further negotiation. Specifically, the letter points out that the parties disagree as to the application of 21 C.F.R. part 56 to studies in India and the need for IRB approval, whether Lannett would have to produce copies of insurance policies relating to its Contract Research Organization, and the dosages of the capsules to be sold to Celgene.

The letter also reveals that the negotiations were ongoing. It speaks of a draft settlement agreement to be circulated. It stated, "the parties will then meet and confer to attempt to resolve any disagreements relating to the contents of the trial protocol, insurance policies, indemnification agreement, protective order, and settlement agreement." Later, in discussing the form of certain documents, counsel wrote, "the parties will continue to work towards resolution of this issue."

### **Discussion**

Settlement agreements are favored by public policy and encouraged as a way of amicably resolving disputes without resort to extensive litigation. *D.R. by M.R. v. East*

*Brunswick Bd. of Educ.*, 109 F.3d 896, 901 (3d Cir. 1997). Whether settlement has occurred is answered according to state law. *Tiernan v. Devoe*, 923 F.2d 1024, 1033 (3d Cir. 1991). Both parties rely on Pennsylvania law in support of their arguments.

Under Pennsylvania law, the enforceability of settlement agreements is governed by principles of contract law. *Pennsbury Village Assoc., LLC v. Aaron McIntyre*, 11 A.3d 906, 914 (Pa. 2011). A settlement agreement will bind the parties “whether or not made in the presence of the court, and even in the absence of a writing.” *Green v. John H. Lewis & Co.*, 436 F.2d 389, 390 (3d Cir. 1970). See also *Beazer East, Inc. v. Mead Corp.*, 412 F.3d 429, 436 (3d Cir. 2005) (“[A] written agreement is not necessary to render a settlement enforceable.”). The fact that the parties intend to formalize their agreement in writing but have not yet done so does not preclude enforcement of the agreement. *Mazzella v. Koken*, 739 A.2d 531, 536 (Pa. 1999).

Oral settlement agreements are enforceable, but only if the parties have agreed upon the essential terms of the bargain. *Krebs v. United Refining Co. of Pa.*, 893 A.2d 776, 783 (Pa. Super. Ct. 2006) (citations omitted). The “nature and extent of the mutual obligations must be certain.” *Id.* (citing *Peck v. Del. Cty. Bd. of Prison Inspectors*, 814 A.2d 185, 191 (Pa. 2002) (internal citations omitted)). As with all contracts, in the formation of an enforceable settlement agreement, “the minds of the parties should meet upon all the terms, as well as the subject-matter.” *Mazzella*, 739 A.2d at 536 (citation omitted). Nonetheless, if there are matters yet to be determined or disagreements about any of the essential terms, there is no agreement to enforce. *Id.* at 537. Preliminary negotiations and agreements to negotiate do not constitute a contract. *Restatement (Second) of Contracts* § 27. In such instances, the parties have yet to determine the essential terms. The burden

of proof is on the party attempting to enforce the settlement to establish that the parties reached an oral agreement. See *Cambria v. Ass'n of Flight Attendants, AFL-CIO*, No. 03-CV-5605, 2005 WL 821082, at \*1 (E.D. Pa. April 5, 2005) (citing *Max Control Sys. v. Indus. Sys.*, No. 99-2175, 2001 WL 1160760 (E.D. Pa. July 30, 2001)).

No written settlement agreement was ever executed. The parties never reached a point in their discussions where all issues had been resolved. The parties engaged in negotiations to settle their differences. Therefore, because there was no settlement agreement, we shall deny the motion.